TERUMO

K090698

Submitter Information:

This submission was prepared in March 2009 by:

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JUN - 8 2009

This submission was prepared for:

Ashitaka Factory of Terumo Corporation
150 Maimaigi-cho, Fujinomiya City
Shizuoka Prefecture
418-0015 Japan
Facility Registration No. 9681834

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Capiox® Bubble Trap with X-coating™	Detector, Bubble, Cardiopulmonary Bypass (KRL)	Bubble Trap

Predicate Device(s):

The device submitted in this 510(k) maintains characteristics that are substantially equivalent to the following devices:

- Capiox® Bubble Trap (K911632).

Intended Use:

The Capiox® Bubble Trap with X-coating™ is a device intended to facilitate air bubble removal from the blood flowing through a cardiopulmonary bypass circuit for up to 6 hours.

Principles of Operation and Technology:

The Capiox® Bubble Trap with X-coating™ is comprised of a single outer housing with no inner housing. This outer housing is cylindrical in shape and has a slight conical-shaped lid assembly affixed to the upper area of the cylinder. The lid assembly has an air vent (purge) port on the top outer surface to facilitate air removal during use. The blood inlet port is positioned along the upper-side axis of the cylinder housing and allows for the entry of blood. The base of the housing contains the blood outlet port.

The cylinder housing contains a screen filter assembly through which blood will pass through for filtration of air bubbles. After the blood has been filtered, it then exits the assembly via the blood outlet port.

Design and Materials:

The materials that are used in the construction of the Capiox® Bubble Trap with X-coating™ include polycarbonate, polyester screen, polyurethane, polyethylene and X-Coating™.

Performance Evaluations:
Terumo Corporation, in conjunction with Terumo Cardiovascular Systems Corporation, conducted the following *in-vitro* performance evaluations to demonstrate the functional equivalence of the Capiox® Bubble Trap with X-coating™ to the predicate (non-coated) BT15 Bubble Trap.

The following tests were performed, and are presented on the ensuing pages:

- Air Removal Efficiency
- Hemolytic Effect Upon Cellular Components of Blood
- Pressure Drop
- Mechanical Integrity/Leakage Evaluation
- Prime Volume

Substantial Equivalence Comparison:
In demonstrating substantial equivalence of the Capiox® Bubble Trap with X-coating™ to the predicate (non-coated) BT15 Bubble Trap, a comparative study and/or assessment was performed in each of the following areas:

- Intended use
- Duration of use/6-hour use
- Product labeling
- Operation and technology of the devices
- Product design
- Materials used in device construction
- Design performance

Substantial Equivalence Statement:
The Capiox® Bubble Trap with X-coating™ is substantially equivalent in intended use, duration of use, labeling, operation and technology, design, materials, and performance to the predicate (non-coated) Capiox® Bubble Trap device.

Additional Safety Information:
- Sterilization conditions for the Capiox® Bubble Trap with X-coating™ are validated in accordance with applicable standards to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo further asserts that the ethylene oxide residues will not exceed stated or implied maximum residue limits at the time of product distribution.

- The X-Coating material that is applied to the blood-contacting surfaces of the devices was evaluated in an *in-vivo* animal study conducted by Terumo Cardiovascular Systems and Sierra Biomedical Laboratories in 1999. No adverse conditions were identified.

Conclusion:
Based upon the comparative studies and analyses, Terumo Corporation concludes that the Capiox® Bubble Trap with X-coating™ is *substantially equivalent* to the predicate (non-coated) Capiox® Bubble Trap device. It is further concluded that any recognized differences noted during the assessments do not raise new issues of patient/user safety or product effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2009

Terumo Cardiovascular Systems
c/o Mr. Garry Courtney
Manager, Quality Systems
125 Blue Ball Rd.
Elkton, MD 21921

Re: K090698
Capiox Bubble Trap with X-coating
Regulation Number: 21 CFR 870.4205
Regulation Name: Detector, Bubble, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: KRL
Dated: May 7, 2009
Received: May 13, 2009

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4
Indications for Use

510(k) Number (if known): Unknown at time of submission K090678

Device Name: Capiox® Bubble Trap with X-coating™

Indications for Use:
The Capiox® Bubble Trap with X-coating™ is a device intended to facilitate air bubble removal from the blood flowing through a cardiopulmonary bypass circuit for up to 6 hours.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D)

OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna B. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090678